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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,862	08/14/2001	Charles L. Shear	PCI1025AADO	9844

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/929,862

Applicant(s)
Charles L. Shear

Examiner
Ray Henley

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed August 14, 2001 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment or prevention of the specific disease/disorders as specified at page 7, line 23 - page 8, line 9 of the present specification, does not reasonably provide enablement for a method of treatment in general wherein no specific therapeutic objective is provided. Such reads on a panacea and the art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. .

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 5, 6, 9-16, 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Deninno et al. (WO 00/17164) who teach methods for treating atherosclerosis, dyslipidemia, hypertriglyceridemia, hypercholesterolemia, cardiovascular disorders, angina (page 22, lines 25-28) through the administration of a composition which may comprise [2R,4S]-4-[(3,5-bis-trifluoromethyl-benzyl)-methoxycarbonyl-amino]-2-ethyl-6-trifluoromethyl-3,4-dihydro-2H-quinoline-1-carboxylic acid ethyl ester (page 9, lines 25-26) and a second compound which may be the HMG-CoA reductase inhibitor atorvastatin (page 29, line 26 and page 30, line 2 and kits containing such compositions (page 30, lines 18-28).

Applicant should note that present claims 19 and 20 are being interpreted as claims directed to a single composition because the statement of intended use, i.e., for use with a second pharmaceutical composition, does not impart any further physical or otherwise material limitation to the claimed composition.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deninno, et al. (as above) in view of Roth (U.S. Patent No. 4,681,893).

The difference between the above and applicant's claimed subject matter lies in that Deninno et al. teach only the compound atorvastatin and not the presently claimed salts and/or hydroxy acid forms thereof.

However, to the skilled artisan, applicant's claimed subject matter would have been obvious because Roth teaches the presently claimed salt forms and hydroxy acid forms of atorvastatin (see the abstract, column 2, lines 3-43 and column 7, lines 1-17) as being effective HMG-CoA reductase inhibitors and the skilled artisan would have been motivated to alternatively use the compounds of Roth for the same purpose as the atorvastatin of Dennino et al. because Dennino et al. teaches atorvastatin for its HMG-CoA reductase inhibitory activity and Roth identifies his compounds as being HMG-CoA reductase inhibitors.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1000

Henley; rjh
January 15, 2002